

### **REMARKS**

This paper responds to the Office Action of September 17, 2009, in which the Examiner objected to claims 32-36, rejected claims 32-36 under 35 U.S.C. § 112, second paragraph, and rejected claims 19-36 under 35 U.S.C. § 102(b).

In response, claims 19, 21, 28, and 31-33 have been amended. In view of the amendments and the following remarks, reconsideration and allowance are respectfully requested.

#### **Claim Objections**

Claims 32-36 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim, claim 32, is unclear.

Claim 32, as amended, is not written in multiple dependent form. Withdrawal of the rejections is thus respectfully requested.

#### **Claim Rejections – 35 USC §112**

Claims 32-36 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim phrase “a drive device as claimed in one of claims 19 through 31,” is not recited in claim 32, as amended. Withdrawal of the rejections is thus respectfully requested.

#### **Claim Rejections – 35 USC §102**

Claims 19-31 are rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,244,465 (Michel). The rejections are traversed for at least the following reasons.

#### **Independent Claim 19 is Not Anticipated by Michel**

Michel does not disclose “wherein . . . a first tension distance . . . is set by translational movement of the tensioning element relative to the housing that tensions the spring device, the

first tension distance corresponding to a first partial advancing distance of the advancing element; the spring device is releasable to drive the advancing element the first partial advancing distance; a second tension distance defined between the counter-element and the advancing element or between the counter-element and the tensioning element is set by an additional translational movement of the tensioning element relative to the housing that tensions the spring device, the second tension distance corresponding to a second partial advancing distance of the advancing element; and each of the first partial advancing distance and the second partial advancing distance is shorter than the total advancing distance,” as recited in claim 19, as amended.

Regarding such a device, Applicants explain:

According to the invention, the distance can be set at the start of the advance and after an advance over a partial advancing distance, i.e. the tensioning device can tension the spring device during the advance of the advancing element without interrupting the force transmission and the advance. The partial advancing distance is shorter than the total advancing distance of the advancing element. The total advancing distance is preferably divided into several partial advancing distances, not necessarily all of the same length, such that a tensioning force can be retensioned and controlled several times during the advance of the advancing element over the total advancing distance. It is also possible to change the force during an advance or after a partial advancing distance and adapt it to new requirements by setting another predetermined distance.

*U.S. 2007/0088290*, para. [0008]

In contrast, Michel discloses a device configured such that “only a single dose can be dispensed from any one ampoule,” and “the dispensing of a second dose of the drug, whether intentional or otherwise, is impossible.” *Michel*, col. 1, ll. 42-43; 47-49. The device includes a housing 1, 10 in which a spring 3 is tensioned between an outer cylinder 24 and an unnumbered housing component, such that the spring 3 drives the outer cylinder 24 and an inner cylinder 23, collectively referred to as the dispensing mechanism 20, to administer a dose. Regarding selection of a dose, Michel explains:

The interior of the housing 22 of the mechanism holder 1 is provided with longitudinal slots 17 of varying length in which the appropriate cam followers 16 of the dispensing mechanism 20 can slide. The stroke of the dispensing mechanism 20 and thus the drug dose which can be discharged is therefore determined by the length of the longitudinal slot 17 in conjunction with the cam follower 16. If the cam follower 16 slides in a short longitudinal slot 17, as

illustrated in FIG. 1, the drug dose is small, whereas if the cam follower 16 slides in a longer longitudinal slot 17" the drug dose is larger. The adaptation of the drug dose to the requirements of the patient is performed solely by the doctor who can release the locking ring 9 of the device by means of a special key which engages a recess 26 of locking ring 9 and loosen it until the cam follower 16 of the dispensing mechanism 20 is disengaged from the relevant longitudinal slot 17. The doctor can now select the desired dose by rotating the disengaged dispensing mechanism 20 and re-engaging the cam follower 16 in a shorter or longer longitudinal slot 17.

*Michel*, col. 3, ll. 9-30.

That is, by rotation of the dispensing mechanism 20, a cam follower 16 of the outer cylinder 24 is aligned with one of several longitudinal slots 17 of varying length, which determines the stroke length (i.e., dose) of the dispensing mechanism 20. Michel does not disclose that the distance between the components supporting the spring 3 (i.e., the tension distance) is adjustable during the dose setting movement. Indeed, the tension distance in the device of Michel is not adjustable until the spring 3 is released to deliver a dose, and upon release, the spring 3 is relaxed, not tensioned. Thus, at best, Michel discloses a device capable of having a single tension distance set with respect to the spring 3 (i.e., the default/initial position), and a subsequent change of this tension distance that relaxes the spring 3. Moreover, once a dose is delivered, the device is rendered inoperable. *See e.g., Michel*, col. 3, ll. 39-45. In contrast, claim 19 recites that "a second tension distance defined between the counter-element and the advancing element or between the counter-element and the tensioning element is set by an additional translational movement of the tensioning element relative to the housing that tensions the spring device."

For at least the foregoing reasons, Michel does not disclose the invention of claim 19. Reconsideration and allowance are thus respectfully requested.

*Independent Claim 30 is Not Anticipated by Michel*

Claim 30 is directed to a method comprising, in part, "advancing the plunger in the direction of the outlet under the force of the drive device by a partial advancing distance which is shorter than the total advancing distance; and after or during the advance of the advancing element over the partial advancing distance, tensioning the spring device by translational movement of the tensioning element relative to the housing."

Applicants submit that claim 30 is patentable over the Michel for at least the reasons discussed above with respect to claim 19 and, further, in view of its additional recitations. Reconsideration and allowance are thus respectfully requested.

*Claims Depending from Claim 19 and Claim 30 are Patentable*

Claims 20-30 and 32-36 depend either directly or indirectly from claim 19 or claim 31. Accordingly, these claims are patentable over Michel for at least the same reasons discussed above and, further, in view of their additional recitations. Reconsideration and allowance are thus respectfully requested.

*Conclusion*

This application now stands in allowable form and reconsideration and allowance are respectfully requested.

This response is being submitted on or before January 19, 2010, and an extension of the time to respond until that date is requested. The required fee should be charged to Deposit Account No. 04-1420. No additional fees should be due in connection with this response, but the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

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